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Attorney Docket No.: 071419-0265228

- AMENDMENT -

**REMARKS**

Reconsideration and the timely allowance of the pending claims, in view of the following remarks, are respectfully requested.

In the Office Action dated May 4, 2005, the Examiner rejected claims 13-16, 64-66, 69, and 72-75, and 78-79, under 35 U.S.C. §102(b), as anticipated by Roberts '786 (U.S. Patent No. 4,754,786); rejected claims 13-18 and 63-91, under 35 U.S.C. §103(a), as being unpatentable over Thompson '166 (U.S. Patent No. 4,710,166) in view of Wortrich '643 (U.S. Patent No. 4,750,643); rejected claims 13-18 and 63-91, under 35 U.S.C. §103(a), as being unpatentable over Orkin '444 (U.S. Patent No. 4,925,444) in view of Wortrich '643; and rejected claims 13-18, 64-70, and 72-91, under 35 U.S.C. §103(a), as being unpatentable over Kampfe '847 (U.S. Patent No. 5,450,847) in view of Wortrich '643.

By this Amendment, Applicant has amended claims 13-18, 63-65, 67-78, 80-88, and 90-91 to provide a clearer presentation of the claimed invention and has cancelled claims 66, 79, and 89, without prejudice or disclaimer of the subject matter contained therein. Applicant submits that no new matter has been introduced.

In addition, Applicant respectfully requests the return of a copy of the initialed PTO-1449 forms in connection with the IDS filed on November 10, 2004.

Applicant respectfully traverses the prior art rejections, under 35 U.S.C. §§102(b), 103(a), for the following reasons:

I. Prior Art Rejections Under §102(b).

As identified above in the claims list section, independent claim 13, as amended, now sets forth a method of delivering fluid to multiple patients. In so doing, claim 13 positively recites providing a fluid delivery system comprising a reusable portion and a plurality of per-patient disposable portions, and connecting the second end of a first per-patient disposable portion of the per-patient disposable portions to the reusable portion and the first end of the first per-patient disposable portion to a first

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patient of the multiple patients to define a fluid path between the first and second fluid sources and the first patient. Claim 13 also positively recites delivering fluid from one or both of the first and second fluid sources to the first patient through the first per-patient disposable portion, disconnecting the first per-patient disposable portion from the reusable portion and the first patient, connecting a second per-patient disposable portion to the reusable portion to a second patient of the multiple patients, and delivering fluid from one or both of the first and second fluid sources to the second patient through the second per-patient disposable portion.

In dramatic contrast, the Roberts '786 reference, is solely directed to the filling of sterilized containers or storage bags with fluids. (See Roberts '786: col. 1, lines 7-9; col. 5, lines 52-55). Roberts '786 discloses the use of a mixing vessel 44, a reservoir container 50, and a pump 54 that pumps the fluid 12 out of the reservoir container 50 and through a filter element 56 via a tube 54d. The fluid 12 then flows through a conduit element 60, and through a plurality of connector elements 62 into storage bags 10 to fill the bags 10. (See Roberts '786: col. 5, line 52 – col. 6, line 52; FIG. 4). There is nothing in the Roberts '786 reference that teaches connecting the second end of a first per-patient disposable portion of the per-patient disposable portions to the reusable portion and the first end of the first per-patient disposable portion to a first patient of the multiple patients to define a fluid path between the first and second fluid sources and the first patient, as required by claim 13. Nor is there anything Roberts '786 that teaches delivering fluid from one or both of the first and second fluid sources to the first patient through the first per-patient disposable portion, disconnecting the first per-patient disposable portion from the reusable portion and the first patient, connecting a second per-patient disposable portion to the reusable portion to a second patient of the multiple patients, and delivering fluid from one or both of the first and second fluid sources to the second patient through the second per-patient disposable portion, as also required by claim 13.

For at least these reasons, Applicant submits that Roberts '786 does not teach each and every element of claim 13, and, therefore, Roberts '786 cannot anticipate claim 13. Moreover, because claims 14-16 and 64-65, 69, 72-75, and 78 depend, either

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directly or indirectly from claim 13, these claims are also not anticipated by Roberts '786. Applicant, therefore, respectfully requests the immediate withdrawal of the rejection of claims 13-16, 64-65, 69, 72-75, and 78, under §102(b).

II. Prior Art Rejections Under §103(a).

The Examiner asserted that the each of the combinations of Thompson '166 and Wortrich '643, Orkin '444 and Wortrich '643, and Kampfe '847 and Wortrich '643 renders independent claim 13 unpatentable. Applicant respectfully disagrees.

Regarding the asserted combination of Thompson '166 and Wortrich '643, Applicant notes that the Thompson '166 reference teaches a system for the sequential delivery of two fluids to *a single patient*. (See Thompson '166: col. 3, lines 51 – 52). As such, Thompson '166 is not capable of teaching a method of delivering fluid to multiple patients.

The Wortrich '643 reference, on the other hand, is directed to dispensing fluid 12 from a *single container 10* to a succession of multiple patients. (See Wortrich '643: col. 3, line 14 – col. 4, line 39; *see also* Abstract; FIG. 1). As such, Wortrich '643 is incapable of teaching a method of delivering two fluids to multiple patients.

There is absolutely no suggestion in either Thompson '166 or Wortrich '643 to combine the features of both to render method of delivering multiple fluids to multiple patients. Given the disparate objectives of Thompson '166 and Wortrich '643, the respective systems are clearly incompatible. As such, it is an unreasonable leap of faith to assert that it would be obvious to artisans of ordinary skill to combine a sequential multiple fluid delivery system to a single patient with a single fluid delivery system for multiple patients. Such an assertion could only be justified by impermissible hindsight.

Regarding the asserted combination of Orkin '444 and Wortrich '643, Applicant notes that the Orkin '444 reference is directed to a closed, multiple-fluid delivery system that can deliver a plurality of preselected fluids in a preselected sequence via a closed fluid-flow delivery system to an output port *for a single patient*. (See Orkin '444: col. 3, lines 34-38; *see also* Abstract). And, as discussed above, Wortrich '643 is

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directed to dispensing fluid 12 from a *single container* 10 to a succession of multiple patients.

Again, there exists no suggestion in either the Orkin '444 reference or the Wortrich '643 reference to combine their respective teachings. And, because the Orkin '444 system is configured to dispense multiple fluids to only a single patient while Wortrich '643 is directed to dispensing a single fluid to multiple patients, these systems are clearly incompatible, so there can be no motivation to combine these two references. It is clear that this combination of references can only be the result of impermissible hindsight.

Finally, with respect to the asserted combination of Kampfe '847 and Wortrich '643, Applicant points out that the Kampfe '847 reference is directed to a system capable of preparing and mixing suitable dosage forms of fluid contrast medium at a concentration and in an amount which are optimal for the individual examination. (See Kampfe '847: col. 3, lines 10-20).

Kampfe '847, however, does not contemplate or suggest *the direct dispensation of fluids to a patient* - much less the capability of delivering fluid to multiple patients. As such, Kampfe '847, clearly fails to teach delivering fluid from one or both of the first and second fluid sources to the first patient through the first per-patient disposable portion and delivering fluid from one or both of the first and second fluid sources to the second patient through the second per-patient disposable portion, as required by claim 13.

Furthermore, Applicants once again point out that two incompatible systems may not be properly combined to render claim 13 unpatentable. Specifically, there is neither a suggestion or motivation to combine the Kampfe '847 system that cannot directly dispense fluids to patients with the Wortrich '643 system that is designed to dispense a single fluid to multiple patients. It is clear that this combination of references can only be the result of impermissible hindsight.

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For at least these reasons, Applicant submits that none of the applied references, can be reasonably combined to teach the claimed combination of elements recited by amended claim 13. As such, claim 13 is clearly patentable over these references. Applicant, therefore, respectfully requests the withdrawal of the rejection of claim 13, under §103(a).

Moreover, because claims 14-16, 64-65, 69, 72-75, and 78 depend, either directly or indirectly from claim 13, these claims are patentable at least by virtue of dependency as well as for their additional recitations.

In addition, independent claims 72 and 82 recite similar features to claim 13 that have been proven to be patentable over the applied references, claims 72 and 82 are patentable for at least the reasons given with respect to claim 13. Further, because claims 73-78 and 80-81 depend from claim 72 and claims 83-88 and 90-91 depend from claim 82, claims 73-78 and 80-81 and claims 83-88 and 90-91 are patentable at least by virtue of dependency as well as for their additional recitations.

### III. Conclusion.

All matters having been addressed, Applicant respectfully requests the entry of this Amendment, the Examiner's reconsideration of this application, and the immediate allowance of all pending claims.

Applicant's Counsel remains ready to assist the Examiner in any way to facilitate and expedite the prosecution of this matter. Please charge any fees associated with the submission of this paper to Deposit Account Number **033975**, Order No. 071419-0265228.

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The Commissioner for Patents is also authorized to credit any over payments to the above-referenced Deposit Account.

Respectfully submitted,

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